Office of the Vice President
Practice Activities
Stanley Zinberg, MD, MS, FACOG
Telephone 202/863-2500
Fax 202/863-4909

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Colin M. Pollard
Chief, Ob/Gyn Devices Branch (HFZ-470)
Office of Device Evaluation
Center for Devices and Radiological Health/FDA
9200 Corporate Boulevard, Rm 210Z
Rockville, MD 20850

Dear Colin:

Thank you for letting us know about the recent publication in the Federal Register of the 1997 FDA Panel recommendation on Corometrics' petition for reclassification of home uterine activity monitors from Class III (premarket Approval) to Class II (special Controls). I do remember that the FDA Panel on Obstetric and Gynecologic Devices did unanimously recommended that FDA approve the petition.

As you know, John Hauth, MD, FACOG represented ACOG at this Panel meeting and outlined numerous concerns that ACOG had regarding this petition (see attached). Also, Larry Gilstrap, MD, FACOG, chair of ACOG's Committee on Obstetric Practice at that time, also identified issues and recent data that reiterated ACOG's concerns on this petition of HUAM. ACOG's Committee Opinion #172 Home Uterine Activity Monitoring represents a review of the literature that has been reaffirmed since its publication in 1995 by ACOG's Committee on Obstetric Practice. The Opinion concludes the following:

> "Well-designed, prospective, randomized clinical studies of sufficient power are still needed to establish the benefit, if any, of HUAM for the prevention of preterm delivery or for the prevention of associated adverse neonatal outcomes...Data are insufficient to support a benefit from HUAM in preventing preterm birth. Therefore, the American College of Obstetricians and Gynecologists does not recommend the use of this system of care."

I believe you will see that ACOG is already on record with its concerns about this petition.

Sincerely,

Stanley Zinberg, MD, MS, FACOG
Vice President, Practice Activities

SZ/DH/lc

Enclosures

cc: Ralph W. Hale, MD, FACOG
Larry Gilstrap, MD, FACOG
Michael Greene, MD, FACOG
John Hauth, MD, FACOG
Terri Gibson
Laura Hanen
Debra A. Hawks, MPH
Mary F. Mitchell
Marsha Simon
Beth Steele

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